REMARKS

Claims 1-101 are currently pending in the present application. Claim 10 is canceled without prejudice to Applicants' right to prosecution the subject matter of this claim in a related application. Claims 1-6, 8, 9, 11-30, 32-34, 36-54, 56-59, 71-74, 77, 78, 81, 84-90, 95-98, 111 and 101 have been amended. Support for these amendments may be found in the specification at least at page 14, lines 22-27; page 15, lines 15-18; page 25, lines 29-30; Section 4.2; and in the claims as originally filed. After entry of the present Amendment, claims 1-9 and 11-101 will be pending.

RESTRICTION REQUIREMENT

The Office Action has required restriction of the pending claims under 35 U.S.C. § 121 to one of the following groups:

I Claims 1-8, 25-33 and 46-49, drawn to a method of modulating the differentiation of a stem cell, the differentiated stem cell that is the product of the method, and a method of using the cell;

II Claims 9-16, drawn to a method of modulation the proliferation of a $CD34^+$ or $CD133^+$ progenitor cell;

III Claims 17-24, drawn to a method of expanding a population of progenitor cells in a mammalian subject;

IV Claims 34-41, drawn to a composition comprising isolated cord blood cells and white blood cells;

V Claims 42-45, drawn to a composition comprising $CD34^+$ or $CD133^+$ progenitor cells;

VI Claims 50-53, drawn to a method of transplanting mammalian progenitor cells;

VII Claims 54-56, drawn to a method of treating an individual experiencing a condition;

VIII Claims 57-70, drawn to a method of treating an individual comprising administering white blood cells;

IX Claims 71-79, drawn to a method of making a composition comprising $CD34^+$ or $CD133^+$ progenitor cells contacted with the recited composition;

X. Claim 80, drawn to a product of the process of Group IX;

XI Claims 81-89 and 101, drawn to a method of modulating the differentiation of $CD34^+$ or $CD133^+$ progenitor cells' and

XII Claims 90-101, drawn to a method of producing differentiated cells from $CD34^+$ progenitor cells.

The Office Action contends that the inventions of Groups I-XII are distinct, each from the other.

Applicant hereby elects, with traverse, to prosecute the invention of Group I, claims 1-8, 25-33 and 46-49, drawn to a method of modulating the differentiation of a stem cell, the differentiated stem cell that is the product of the method, and a method of using the cell. As Applicants have amended claims 9-16 to depend from claim 1, these claims should be included within the elected group.

With respect to the alleged lack of unity of invention of each of the groups with each other group, Applicants respectfully traverse and request that the Requirement be withdrawn. Applicants submit that (i) the basis for restriction is not legally sufficient; and (ii) there is a technical relationship among the different groups that involves at least one common special technical feature such that the inventions are linked to form a single general inventive concept (*see* World Intellectual Property Organization Administrative Instructions Under the Patent Cooperation Treaty, Annex B).

First, "[w]hen making a lack of unity of invention requirement, the examiner must (1) list the different groups of claims and (2) explain why each group lacks unity with each other group . . . *specifically describing the unique special technical feature in each group.*" *See* M.P.E.P. 1893.03(d) (emphasis added). Rather than explain why each group lacks unity or specifically describe the unique technical feature in each group, the Office action merely concludes that, aside from Group I, "[o]ther methods and products are paced in individual groups, as PCT rule 13.2 does not provide for multiple methods of products in a single category." Office action at page 3. As such, this basis for restriction is not legally sufficient. Applicants therefore respectfully request that the election requirement be withdrawn.

Second, the invention, as embodied in the claims, does in fact form a single general inventive concept and, as such, the claims should each be examined in the instant application. This is particularly true for the claims of Groups I-VI, XI and XII. Unity of invention exists where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. "Special technical feature" in this context means those technical features that define a contribution which each of the

inventions, considered as a whole, makes over the prior art. *See* World Intellectual Property Organization Administrative Instructions Under the Patent Cooperation Treaty, Annex B.

Under this standard, Applicants submit that at least Groups I-VI, XI and XII share a technical relationship so as to form a single general inventive concept. At the root, the present application discloses the contacting of stem or progenitor cells with a compound of the invention, a phosphodiesterase IV inhibitor.

With respect to Groups I and II, Applicants have amended claim 9 to depend from claim 1. Thus, claims 9-16, identified as Group II in the Office Action, share at least one common technical feature with Group I: contact of a stem cell or progenitor cell with a PDE IV inhibitor. Likewise, the claims of Group III encompass contacting a stem cell or a progenitor cell with a PDE IV inhibitor. The claims of Group IV, claims 34-41, are directed to a composition comprising cells differentiated from stem cells or progenitor cells contacted with a PDE IV inhibitor; as such, these claims share the technical feature common to Groups I-III (*see* particularly claims 25-33 of Group I). Claims 42-45, Group V, are also directed to cells that have been contacted with a PDE IV inhibitor; as such, these claims define essentially a subset of the subject matter of claims 25-33 of Group I. Moreover, Group I should also include the claims of Group VI, which are directed to a method of transplanting a progenitor cell. Both claims 46-49 of Group I and Group VI, claims 50-54, are directed to transplanting a cell that has been contacted with a PDE IV inhibitor sufficient to modulate differentiation of the cell. Thus, claims 50-54 share at least one significant technical feature with the claims of Group I. In the same manner, the claims of Group XI and Group XII are directed to a method of differentiation of a progenitor cell by contacting the cell with a PDE IV inhibitor, and a method of producing a differentiated cell by contacting a particular type of progenitor cell with a PDE IV inhibitor.

Thus, at least Groups I-VI, XI and XII share at least the technical feature of contacting a stem or progenitor cell with a PDE IV inhibitor, and all relate to the method of contacting, the products of the contacting, or the use of those products. As a result these claims, at least, form a "single general inventive concept" recognized in the art of stem cell culture. Applicants therefore respectfully request that the Examiner withdraw the election requirement with respect at least to these groups of claims, and examine at least claims 1-53 and 81-101 together.

SPECIES ELECTION REQUIREMENT

The Office Action additionally requires election of certain species. Again, the Office action does not set out the reasons that the recited species lack unity of invention. Applicants point out that, because unity of invention exists, as explained above, a species election requirement is not proper. Moreover, many of the species listed in the Office Action at page 3 do share technical features so as to form a single inventive concept. For example, stem cells (a)-(e) are each a stem cell. Likewise, progenitor cells (j)-(k) are each a progenitor cell; $CD34^+CD38^-CD33^+$ cells (l) and $CD34^+CD38^-CD33^-$ cells (m) are both $CD34^+CD38^-$ cells; hematopoietic cells (n)-(p) are each a hematopoietic cell; and human stem cell (s) and progenitor cell (t) are each a differentiable cell (indeed, the Office action refers to both as "stem cells"). Moreover, the common technical feature among the claims—the contact of a stem or progenitor cell with a PDEIV inhibitor, including $CD34^+CD38^-$ cells and hematopoietic cells—is common to at least these species, as well. Applicants therefore respectfully request that the species election requirement be withdrawn. However, to fully comply with the species election requirement, Applicants provisionally elect species, with traverse, as follows:

- Type of stem cell (embryonic stem cell; placental stem cell; cord blood stem cell; peripheral blood cell; or bone marrow blood cell).
  Applicant provisionally elects placental stem cells.
- A SelCID (selective cytokine inhibitory drug) or prodrug of a SelCID.
  Applicant provisionally elects a selective cytokine inhibitory drug.
- Differentiation in cell culture or in an individual.
  Applicant provisionally elects differentiation in an individual.
- Hematopoietic cell types ($CD34^+$, $CD38^+$, or $CD11c^+$).
  Applicant provisionally elects $CD34^+$ cells.

Applicants respectfully also note that the species elections are made with traverse because it would not be an undue burden to examine all species together. For example, each of the stem cell types listed in the Office action is a "stem cell," and would be easily searchable using the generic term. Likewise, each of the hematopoietic cell types would be searchable using the term "hematopoietic"; the $CD34^+CD38^-CD33^+$ and $CD34^+CD38^-CD33^-$ cells would be easily searchable using the term "$CD34^+CD38^-$"; and searching for "stem" and "progenitor" cells in the same search would search approximately the same subject matter. Claims readable on the provisionally-elected species are claims 1-6, 8, 25-32 and 46-49.

CONCLUSION

Applicants respectfully request that the present remarks be made of record in the file history of the present application. An early allowance of the application is earnestly requested. The Examiner is invited to contact the undersigned with any questions concerning the application.

Respectfully submitted,

Date October 6, 2005

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Enclosure